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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/551,687

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Robert Moszner

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AKERMAN SENTERFITT
801 PENNSYLVANIA AVENUE N.W.
SUITE 600
WASHINGTON, DC 20004

EXAMINER

OU, JING RUI

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/551,687	Applicant(s) MOSZNER ET AL.	
	Examiner JING OU	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/30/2005, 10/03/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is responsive to the preliminary amendment filed on September 30, 2005. Claims 1-14 are pending. Claims 1 and 10 are independent.

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "fabric insert" in claim 9 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate

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changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

4. Claims 1 and 14 are objected to because of the following informalities:
 - a. In the preamble of Claim 1, the term "consisting" should be replaced by "comprising."
 - b. In line 4 of Claim 14, the phrase "the the" should be replaced by "the."

Appropriate correction is required.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claim 1 is provisionally rejected on the ground of nonstatutory double patenting over claim 1 of copending Application No. 11/271,752. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation, "the braiding tapers to a diameter of one of a plurality of catheters used in the intravascular surgical procedure" is being unclear. Examiner interprets the

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recitation as "the occlusion device having a taper end having a diameter suitable for delivered by a catheter used in the intravascular surgical procedure."

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 2, 5-11, 13, and 14 rejected under 35 U.S.C. 102(b) as being anticipated by Kotula et al (US Pat. No.: 5,846,261).

In regard to Claim 1, Kotula et al discloses an occlusion device (ASD device, 140, Fig. 24) comprising of a braiding of thin wires (Fig. 15 and Col. 2, lines 51-59) given a suitable form by means of a molding and heat treatment procedure (Fig. 24 and Col. 7, lines 40-67 and Col. 8, lines 1-30), having a proximal retention area (expanded diameter portion, 144, Fig. 24) and a distal retention area (expanded diameter portion, 142, Fig. 24), whereby the ends of the wires or threads converge into a holder (clamp, 152, Fig. 24) in the distal retention area, and having a cylindrical crosspiece (reduced diameter portion, 146, Fig. 24) interposed between said proximal and distal retention areas, wherein a proximal retention area of the braiding exhibits a flaring toward a proximal end (Fig. 24).

In regard to Claim 2, the braiding is composed of nitinol or of another shape-memory material (Col. 5, lines 66-67).

In regard to Claim 5, the occlusion device has a taper end having a diameter (Fig. 15) suitable for delivered by a catheter used in the intravascular surgical procedure (see Abstract).

In regard to Claim 6, a proximal retention area of braiding exhibits a flattened tulip-shaped flared contouring to the proximal end (Fig. 24).

In regard to Claim 7, the proximal retention area of the braiding exhibits a bell-shaped flared contouring to the proximal end (Fig. 24).

In regard to Claim 8, the wires of the braiding at the open end of the proximal retention area are looped back to the closed end of the distal retention area and secured there in a holder (clamp 152 of the expanded diameter portion 144, Fig. 24). The wires of the expanded diameter portion 144 are looped back in a direction toward the clamp of the expanded diameter portion 142 and secured there in the clamp 152 of the expanded diameter portion 144).

In regard to Claim 9, at least one fabric insert is arranged in crosspiece or in the proximal retention area (Col. 5, lines 32-42, since a metal planar fabric is a more conventional fabric and may take the form of a flat woven sheet, knitted sheet or the like, the fabric insert is arranged throughout the filter when the filter is formed of fabric).

In regard to Claims 10 and 11, the method is inherent in the prior art reference since the method of manufacturing the filter 140 must be comprising: a) configuring a funnel-shaped hollow (combination of recesses 148, 150 and reduced diameter portion 146) braiding, whereby said hollow braiding is bundled at a first distal end and remains open on an opposite second proximal end (Fig. 24); and b) forming a proximal retention

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area at the open second end, a distal retention area at the bundled first end, and interposing a cylindrical crosspiece between said proximal and said distal retention areas (Fig. 24); and the method further configuring a holder (152 of the expanded diameter portion 142) at the bundle distal end of said funnel-shaped hollow braiding.

In regard to Claim 13, the step of forming retention areas and crosspiece includes a molding and/or heat treatment (Col. 7, lines 40-67 and Col. 8, lines 1-30 and 46-56)

In regard to Claim 14, a funnel-shaped hollow braiding structure is produced such that the thin wires that constitute finished braiding are intertwined at the proximal open end of the braiding when the funnel-shaped hollow braiding is formed (Fig. 24, the wires are intertwined at the expanded diameter portion 144).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 3, 4, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kotula et al (US Pat. No.: 5,846,261).

In regard to Claims 3 and 4, Kotula et al discloses all the limitations of the claims as taught above but fails to disclose that the braiding is formed from a shape-memory polymer, preferably based on a polyanhydride matrix or on polyhydroxycarboxylic acids or of a block copolymer form. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the braiding of Kotula to be formed from a shape-memory polymer based on a polyanhydride matrix or on polyhydroxycarboxylic acids or of a block copolymer form, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

In regard to Claim 12, Kotula et al discloses all the limitations of the claims as taught above and further discloses the wires and threads of the braiding at the outer

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edge of the-flattened tulip shape of the open end of the proximal retention area are looped back to the closed end of the distal retention area and are bundled and secured there in a second holder (clamp 152 of the expanded diameter portion 144, Figs. 15 and 24). Kotula et al does not appear to explicitly disclose that the wires and threads of the braiding are bundled and secured in the holder of the distal retention area.

However, it is only a design choice and within level of one of ordinary skill in the art to design the wire to be looped back to the closed end of the distal retention area and are bundled and secured there in the holder. In addition, it is old and well known in the art to design the wire to be looped back to the closed end of the distal retention area and are bundled and secured there in the holder.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Kotula to include that the wires and threads of the braiding are bundled and secured in the holder of the distal retention area.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Kotula et al (US Pat. No.: 5,725,552)

Amplatz et al (US Pat. No.: 5,944,738)

Flament et al (US Pat. No.: 6,180,848)

Amplatz (US Pat. No.: 6,368,339)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JING OU whose telephone number is (571)270-5036. The examiner can normally be reached on M-F 7:30am - 5:00pm, Alternative Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Uyen (Jackie) T Ho can be reached on (571)272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JRO

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773